

Remarks

I. Status of the Claims and the Specification

Upon entry of the foregoing amendments, originally submitted in the Amendment and Reply of October 18, 2006, claims 1-15, 19, 21-34, 55 and 61-63 and 68-96 are pending in the application, with claims 1 and 63 being the independent claims. Claims 16-18, 20, 35-54, 56-60 and 64-67 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Pending claims 5, 9, 10, 12 and 30 have been withdrawn from consideration by the Examiner as not being directed to an elected species.

Amendment is sought to claims 1, 25, 30, 55, 63, 70-71, and 77, and new claims 91-96 are sought to be entered. These amendments and new claims are supported, *inter alia*, by the originally filed claims and specification. In particular for the currently amended claim 1, the added feature "wherein said ghrelin peptide comprises an amino acid sequence of SEQ ID NO: 119" was originally disclosed, *inter alia*, in original claim 25 as filed. For the currently amended claim 63, the added feature "wherein said core particle comprises a virus-like particle of an RNA-bacteriophage" can be found in original claim 2 of the application as filed. Hence these amendments do not introduce new matter, and their entry and consideration are respectfully requested.

II. Summary of the Notice of Non-Responsive Amendment

In the Notice of Non-Responsive Amendment (Form PTO-90C) issued January 26, 2007, the Examiner asserted that the amendment filed October 18, 2006 was allegedly noncompliant for the following reasons:

(1) the amendment has allegedly effectively canceled all claims drawn to the elected invention and has presented only claims drawn to the non-elected invention; and

(2) the amended claims allegedly are not readable on the elected invention because the claims recite non-elected subject matter. Applicants respectfully traverse the Examiner's assertions, for at least the following reasons.

The Examiner asserts in the Notice of Non-Responsive Amendment of January 26, 2007, that the elected species are limited to SEQ ID NO: 4 and SEQ ID NO: 65, and that they have been effectively cancelled because of Applicants' amendment to claim 1, inserting SEQ ID NO: 119. Contrary to the Examiner's assertion, the elected species in the presently pending application are Q-beta phage and SEQ ID NOs: 4, 31 and 65.

In the Office Action (hereinafter "OA") of January 12, 2006 the previous Examiner, Tim Brown, indicated that Applicants elected the species Qβ-bacteriophage and SEQ ID NO: 31 in a telephonic interview on November 28, 2005. In the OA, the Examiner required an additional election of species from claims 12, 25 and 30.

In Applicants' Amendment and Reply of May 4, 2006, Applicants indicated that "[f]or purposes of search and examination, Applicants' representative elected the species (xiii), Qβ-bacteriophage which is recited in claims 4, 7, 8, 14, 43 and 48 and the ghrelin peptide having the sequence of SEQ ID NO: 31, which is recited in claims 25, 52 and 53" (Amendment and Reply of May 4, 2006, page 23.) Applicants traversed the Election/Restriction. However, Applicants also noted that in case the traversal was not found persuasive, Applicants would additionally elect SEQ ID NO: 4 (claim 12) of a bacteriophage Qβ core particle, and SEQ ID NO: 65. Thus, after the first action and response the elected species are Qβ-bacteriophage, and SEQ ID NOs: 4, 31 and 65.

In the second non-final OA, the present Examiner acknowledged the election of the additional species SEQ ID NO: 4 and 65. However, the Examiner did not mention the previously elected species of Q β -bacteriophage and SEQ ID NO: 31 made during the telephonic interview with Examiner Brown, which Examiner Brown had previously acknowledged on the record. The present Examiner also did not address Applicants' traversal of the Election/Restriction election requirement in Applicants Amendment and Reply of May 4, 2006. Because the telephonic species election was entered by Examiner Brown and has never been withdrawn by the Office nor by Applicants, the elected species are Q β -bacteriophage, and SEQ ID NOs: 4, 31 and 65.

The claims as currently pending (*i.e.* upon entry of the amendments in Applicants reply of October 18, 2006) require that the ghrelin peptide of the invention encompass a 7 amino acid sequence GSSFLSP (SEQ ID NO: 119). SEQ ID NO: 119 is a common structural feature in all of the remaining sequences set forth in the presently pending claims. The location of GSSFLSP (SEQ ID NO: 119) in the claimed sequences is shown below:

GSSFLSPEHQRVQRKESKKPPAKLQPR (SEQ ID NO: 48);
GSSFLSPEHQRVQQRKESKKPPAKLQPR(SEQ ID NO: 31); *
GSSFLSPEHQKLQQRKESKKPPAKLQPR(SEQ ID NO: 49);
GSSFLSPEHQKLQRKESKKPPAKLQPR(SEQ ID NO: 50);
GSSFLSPEHQKAQQRKESKKPPAKLQPR(SEQ ID NO: 32);
GSSFLSPEHQKAQRKESKKPPAKLQPR(SEQ ID NO: 51);
GSSFLSPEHQ(SEQ ID NO: 55);
GSSFLSPEHQRVQ (SEQ ID NO: 60);
GSSFLSPEHQKLQ (SEQ ID NO: 62);
CGSSFLSPEHQRVQRKESKKPPAKLQPR(SEQ ID NO: 64);
CGSSFLSPEHQRVQQRKESKKPPAKLQPR(SEQ ID NO: 65); *
CGSSFLSPEHQKLQQRKESKKPPAKLQPR(SEQ ID NO: 71);

GSSFLSPEHQKLQRKESKKPPAKLQPR(SEQ ID NO: 72);
GSSFLSPEHQKAQQRKESKKPPAKLQPR(SEQ ID NO: 77);
GSSFLSPEHQKAQRKESKKPPAKLQPR(SEQ ID NO: 106) ;
GSSFLSPEHQRVQRKESKKPPAKLQPRC(SEQ ID NO: 66);
GSSFLSPEHQRVQRKESKKPPAKLQPRGC (SEQ ID NO: 120);
GSSFLSPEHQRVQQRKESKKPPAKLQPRC(SEQ ID NO: 67);
GSSFLSPEHQRVQQRKESKKPPAKLQPRGC (SEQ ID NO: 121);
GSSFLSPEHQKLQQRKESKKPPAKLQPRC(SEQ ID NO: 73);
GSSFLSPEHQKLQQRKESKKPPAKLQPRGC (SEQ ID NO: 123);
GSSFLSPEHQKLQRKESKKPPAKLQPRC(SEQ ID NO: 74);
GSSFLSPEHQKLQRKESKKPPAKLQPRGC (SEQ ID NO: 124);
GSSFLSPEHQKAQQRKESKKPPAKLQPRC(SEQ ID NO: 105);
GSSFLSPEHQKAQRKESKKPPAKLQPRC(SEQ ID NO: 107);
GSSFLSPEHQC(SEQ ID NO: 110);
GSSFLSPEHQRVQC (SEQ ID NO: 68);
GSSFLSPEHQRVQGC (SEQ ID NO: 122);
GSSFLSPEHQKLQC (SEQ ID NO: 75);
GSSFLSPEHQKLQGC (SEQ ID NO: 125);
GSSFLSPEHQKAQRKESKKPPAKLQPRC (SEQ ID NO: 126);
GSSFLSPEHQKAQRKESKKPPAKLQPRGC (SEQ ID NO: 127);
GSSFLSPEHQKAQQRKESKKPPAKLQPRC (SEQ ID NO: 128);
GSSFLSPEHQKAQQRKESKKPPAKLQPRGC (SEQ ID NO: 129);
GSSFLSPEHQKAQGC (SEQ ID NO: 130);
GSSFLSPEHQKAQGC (SEQ ID NO: 131);
GSSFLSPEHQGC (SEQ ID NO: 132).

* Note: asterisks and italics denote the elected species.

Thus, GSSFLSP (SEQ ID NO: 119) is a common structural feature that is found in all of the sequence species directed to the ghrelin peptide. In the present case, the Examiner has already searched SEQ ID NOs: 31 and 65, and both sequences comprise GSSFLSP (SEQ ID

NO: 119). In conducting a search for SEQ ID NOs: 31 and 65, SEQ ID NO: 119 therefore has already been searched by default. Hence, the addition of SEQ ID NO: 119 into independent claim 1 does not equate to a cancellation of the elected species SEQ ID NOs: 31 and 65, since both of the elected sequences clearly comprise SEQ ID NO: 119.

The Examiner has asserted that the amendment of October 18, 2006, is non-compliant as being non-responsive in accordance with MPEP §821.03. However, the practice set forth in MPEP §821.03 is not applicable where a provisional election of a single species was made in accordance with MPEP § 803.02, and where Applicant now presents claims that could not have been restricted from the elected invention had the claims been presented earlier. MPEP §821.03. The Amendment and Reply of October 18, 2006, canceled all sequences that did not comprise SEQ ID NO: 119 from the claims. As such, this is the first time that the claims could have been presented with the limitation of SEQ ID NO: 119 in the generic claim. Because the remaining sequences all comprise SEQ ID NO: 119, they share a common structural element. *See In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980). Prior to the cancellation of the sequences that do not comprise SEQ ID NO: 119, claim 1 could not have been presented with this limitation. Hence, the Examiner's reliance on MPEP §821.03 is legally and factually without basis.

Applicants respectfully assert that the amendment to claim 1 inserting SEQ ID NO: 119 has not effectively canceled the elected species of Q β -bacteriophage and SEQ ID NO: 4, 31 and 65. The insertion of SEQ ID NO: 119 into claim 1 does not effect the search or examination of Q β -bacteriophage SEQ ID NO: 4, because that elected species is directed to the core particle and not to the ghrelin peptide. All remaining presently claimed ghrelin sequences comprise **GSSFLSP** (SEQ ID NO: 119), including the elected species SEQ ID

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NO: 31 and 65 as shown above in the listed sequences. Therefore, the addition of the recitation of SEQ ID NO: 119 in claim 1 in the Amendment and Reply of October 18, 2006, is proper, and Applicants' reply thus is fully responsive. Applicants respectfully request that the Notice of Non-Responsive Amendment be reconsidered and withdrawn, and that the amendments and remarks presented in Applicants' Amendment and Reply filed October 18, 2006, be entered and considered.

Conclusion

Applicants believe that a complete reply has been made to the outstanding Office Action(s), and that this reply is fully compliant with 37 C.F.R. 1.145. As such, Applicants respectfully assert that the present application is in condition for allowance.

All of the stated grounds of rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable entry and consideration of this Reply to Notice of Non-Responsive Amendment, together with the Amendment and Reply filed on October 18, 2006, are respectfully requested.

Respectfully submitted,

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